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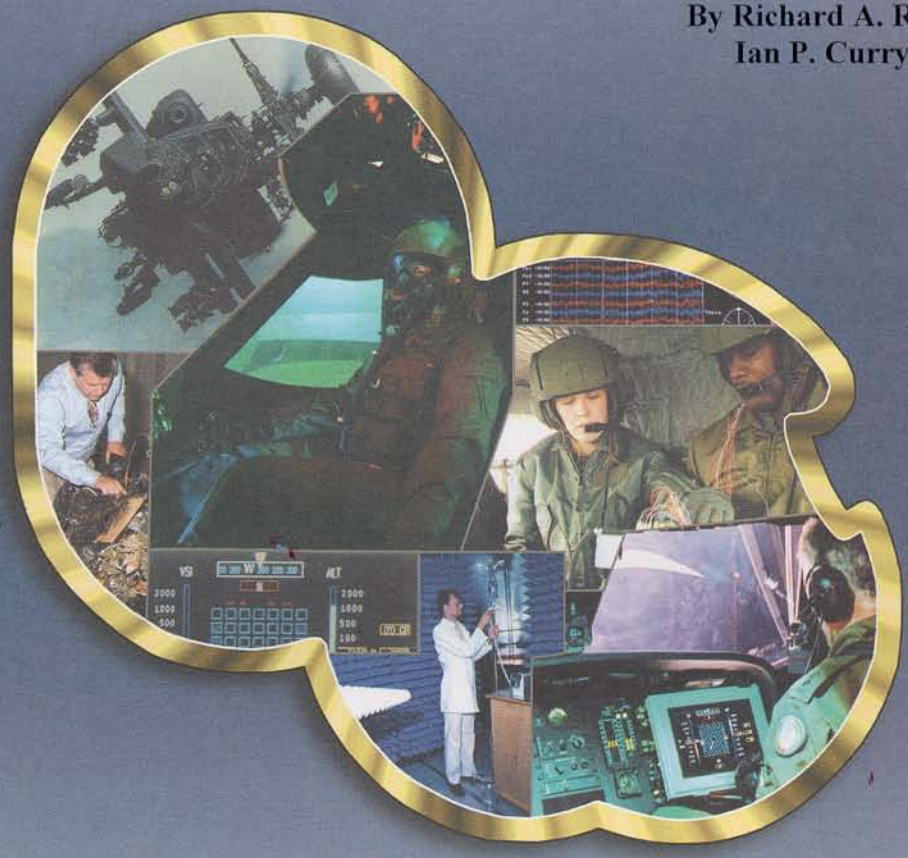
Evaluation of a Gentex® ORO-NASAL Oxygen Mask for integration with the Aqualung® Personal Helicopter Oxygen Delivery System (PHODS)

By Richard A. Roller
Ian P. Curry



Sensory Research Division

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14. ABSTRACT

In current U. S. Army operations, rotary-wing aircrew can be repeatedly exposed to moderately high altitude (up to 18,000 feet pressure altitude), making hypoxia, and its performance effects, a real hazard. The United States Army Aeromedical Research Laboratory (USAARL) was tasked by the Product Manager Air Warrior to evaluate an oxygen mask for use with the Personal Helicopter Oxygen Delivery System (PHODS) for potential use by U. S. Army helicopter aircrew. The mask was tested on pilot volunteers at altitude to determine efficacy. The mask and PHODS was able to maintain aircrew blood oxygen at acceptable levels up to and including 18,000 feet.

15. SUBJECT TERMS

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Introduction

Current U.S. Army operations are exposing rotary wing aircrew to repeated incidences of moderately higher altitudes (up to 18,000 ft pressure altitude). The current flight regulations (AR 95-1) list the following requirements for flight at altitude:

"Approved oxygen systems will be used as follows:

Unpressurized Aircraft.

Oxygen will be used by aircraft crews and occupants for flights as shown below:

(1) Aircraft crews.

(a) On flights above 10,000 feet pressure altitude for more than 1 hour.

(b) On flights above 12,000 feet pressure altitude for more than 30 minutes.

(2) Aircraft crews and all other occupants.

(a) On flights above 14,000 feet pressure altitude for any period of time.

(b) For flights above 18,000 feet pressure altitude, oxygen pre-breathing will be accomplished by aircrew members. Prebreathing may utilize either 100 percent gaseous aviator's oxygen from a high pressure source, or an onboard oxygen generating system (OBOGS) that supplies at least 90 percent oxygen in the inspired gas. Prebreathing will be for not less than 30 minutes at ground level and will continue while en route to altitude. In those extraordinary cases where mission requirements dictate rapid ascent, commanders may authorize shorter prebreathing times on a case-by-case basis, with the realization that such practice increases the risk for developing altitude decompression illness. Return to normal oxygen (pressure demand regulator, gaseous oxygen-equipped aircraft) is authorized on descent below 18,000 feet pressure altitude, provided continued flight will not exceed this altitude."

In-theater operations involving AH-64, MH-60 and OH-58 aircraft are currently utilizing a non-proven portable oxygen system and are subject to hazard as a result. These aircraft types have significant weight and space limitations which preclude the use of oxygen concentrator or heavy cylinder systems.

Referring to the oxygen dissociation curve, the figure of 80% hemoglobin oxygen saturation (SpO_2) which refers to an adequate partial pressure of Arterial Blood Oxygen (PaO_2) (Pickard, 2002) is accepted as the level where tissue oxygen perfusion can begin to be compromised and the effectiveness of the system will be assessed against this benchmark. In a similar study, Joshi and Thakur (2004) selected 65% SpO_2 safety cut off when they exposed aircrew up to 21,000 ft in an altitude chamber with no reported adverse events.

Background

Given the current and possibly future theaters of operation for Army Aviation, there is an immediate need for a safe and effective portable oxygen delivery system for aircrew. The U.S. Army Aeromedical Research Laboratory (USAARL) has previously evaluated the Aqualung® Personal Helicopter Oxygen Delivery System (PHODS) (Curry & Roller, 2007). This system (figures 1 through 4) has been modified in accordance with the USAARL's recommendations and is currently scheduled for use by U.S. Army Aviation. During that previous investigation it was determined that at moderate altitudes (> 15,000 ft) and under conditions of exercise, aircrew may desaturate while using that system if they breath through their mouth and not through the nasal cannula (figure 3). During testing a prototype Gentex® oxygen (O_2) face mask was evaluated with the system and found to not adequately protect against hypoxia at altitude; in fact, the nasal cannula provided better oxygenation than the mask at 18,000 ft (Curry & Roller, 2007). Our previous study suggested that certain Army aircrew (e.g., CH-47 crew chiefs) may desaturate at altitude while using the PHODS equipped with nasal cannula if they are physically active or happen to respire more through their mouths than nasal passages. Dedicated training in the use of the PHODS system and the importance of breathing through the nasal cannula was recommended by the USAARL (Curry & Roller, 2007).

Figure 1. Aqualung® Personal Helicopter Oxygen Delivery System (PHODS).

Figure 2. Aqualung® Oxygen Pulse Controller (OPC).

Figure 3. Aqualung® PHODS in typical aviation configuration.

Figure 4. Gentex® oxygen mask attached to HGU-56/P helmet.

Product Manager (PM) Air Warrior had requested that the USAARL evaluate a re-designed Gentex® Oxygen mask (figures 4, 5a, and 5b) for integration with the Aqualung® PHODS. The mask, manufactured by Gentex, is a modification of the standard MBU-20 intended to be mounted on HGU-56/P using the maxillofacial shield retention clip, quick disconnects (figures 5c and 6). According to Gentex, the mask integrates with the face shield, meaning that the mask can be worn inside and attached to the face shield/helmet or attached directly to the HGU-56/P helmet by itself. The mask is made of soft black rubber that conforms to face size variations. There are six sizes. Standard U.S. Army compatible communications microphone is integrated and compatible with M1 pulse regulator. The mask nose clip provides valsalva capability. This system will potentially be used by U.S. Army aircrew flying at moderately high altitudes (up to 18,000 ft) to support the Global War on Terrorism (GWOT). It was thought that this full face mask would provide better oxygenation for physically active aircrew at altitude, than that provided by the nasal cannula alone.

Figure 5a. Gentex® PHODS experimental O_2 mask & maxillofacial shield for aircrew.

Figure 5b. Gentex® PHODS experimental O_2 mask for aircrew.

Figure 5c. Close-up of quick-release snap for mask attachment.

Objectives

The aim of this study was to measure the effectiveness of the Gentex® PHODS O_2 Mask coupled with the Aqualung® PHODS in ameliorating hypoxia effects on rotary aircrew at moderate altitude exposure (up to 18,000 ft).

Specific objectives were to:

a. Test whether the mask coupled with the system provides adequate oxygenation (higher than 80% SpO_2) at rest (simulating the pilot role) and during moderate exercise (simulating the crew chief/gunner role). Two criterion values were selected: 91%, above which no cognitive deficit is expected, and 80%, below which significant cognitive deficits are more frequent (Ernsting and Young 2006).
b. Compare the efficacy of the mask to the nasal cannula in preventing hypoxia, and the results of this study were compared to the previous USAARL study of the Aqualung® PHODS equipped with the nasal cannula (Curry & Roller, 2007).
c. Accurately measure average oxygen consumption using both cannula and mask configurations. These data were used to estimate the endurance of each bottle of oxygen in all conditions.

Experimental design

Instrumentation

One mask was evaluated during this study: Gentex® mask (figures 5a through 5c). This mask was evaluated with the previously tested Aqualung® Personal Helicopter Oxygen Delivery System (PHODS) (figures 1 and 2). The mask was attached to the PHODS and the HGU-56/P Helmet. The mask can be used either alone (figure 4) or attached to the maxillofacial shield (figure 6) and can be used in lieu of the nasal cannula (figure 3). In this evaluation the maxillofacial shield was not attached nor evaluated with the mask.

Figure 6. PHODS with O_2 mask inside maxillofacial shield.

The Aqualung® PHODS is man-mounted (figures 1 through 4 and 6) and delivers oxygen from a standard and portable steel Survival Egress Air (SEA) bottle (located on the survival vest) via nasal cannula or oro-nasal mask to the aircrew member. A unique feature of this apparatus is the inclusion of the Oxygen Pulse Controller (OPC) (figure 2) which according to the manufacturer (Mountain High® Corp.), automatically provides "on-demand" oxygen regulated to altitude by detected barometric pressure (pressure altitude); which is unlike the system presently used by aircrew. There are several aspects of airworthiness such as human factors and aircraft integration that was addressed by the previous study (Curry & Roller, 2007). The purpose of the current investigation is to determine if the Gentex® mask, coupled with the previously tested Aqualung® PHODS will adequately protect aircrew from hypoxia at altitude and to determine its ease of use by aircrew when integrated with the current system.

The Aqualung® OPC (figure 2) was described in a previous USAARL Technical Report (Curry & Roller, 2007). Its function is to automatically regulate the oxygen flow to both the mask and nasal cannula with respect to the ambient barometric pressure altitude. The controller has four settings:

1. OFF
2. Fully-Automatic (ON)
3. Manual (R/M)
4. Semi-Automatic/Facemask (F20)

The fully automatic setting (ON) is used with the nasal cannula, starts delivering O_2 at 10,000 ft PA and is fully automatic (requires no adjustment as altitude is changed). The F20 setting is designed to be used with the face mask during "normal" flying. It must be turned on manually and continuously delivers O_2 (still by on-demand inspiration) while the setting F20 is on. The Manual R/M (Reserve/Manual) setting was intended (according to Aqualung) to be used in "emergency situations" when additional airflow was required. The R/M setting is still an "on demand" setting and O_2 delivery to the mask is triggered by inspiration; however, it provides the maximum oxygen flow regardless of altitude. The purpose of this study was to evaluate the mask on its standard setting (F20) and the nasal cannula; therefore, the mask on R/M was not evaluated under exercise conditions. Since the mask on R/M setting did provide significantly better oxygenation ($p < 0.05$) it may be desirable to use this setting in conditions where additional O_2 is required (e.g. exercise, stress, combat). The downside to continuously utilizing the R/M setting (in routine flying) is that it depletes the O_2 reserve of the bottle much more rapidly (duration < 1 hour) than either a setting of F20 or using the nasal cannula (table 2).

Testing

The testing was performed on volunteer aircrew members utilizing the Federal Aviation Administration (FAA) Civil Aerospace Medical Institute's (CAMI) altitude chamber in Oklahoma City (figure 7). The subjects were recruited from neighboring military installations and FAA-certified civilian aviation schools. All military subjects had a current Flying Duty Medical Exam ("flight physical") and possessed a valid DA 4186 ("upslip"). All civilian subjects had a current FAA Physical exam. All subjects were medically screened by U.S. Army and FAA flight surgeons (physicians) during the enrollment process. This ensured that all subjects were medically/physically fit and had no condition which placed them at risk during the study. The study population was limited to aircrew as it was felt that this ensured a greater safety margin, and best represented those individuals who will be using this system in the field.

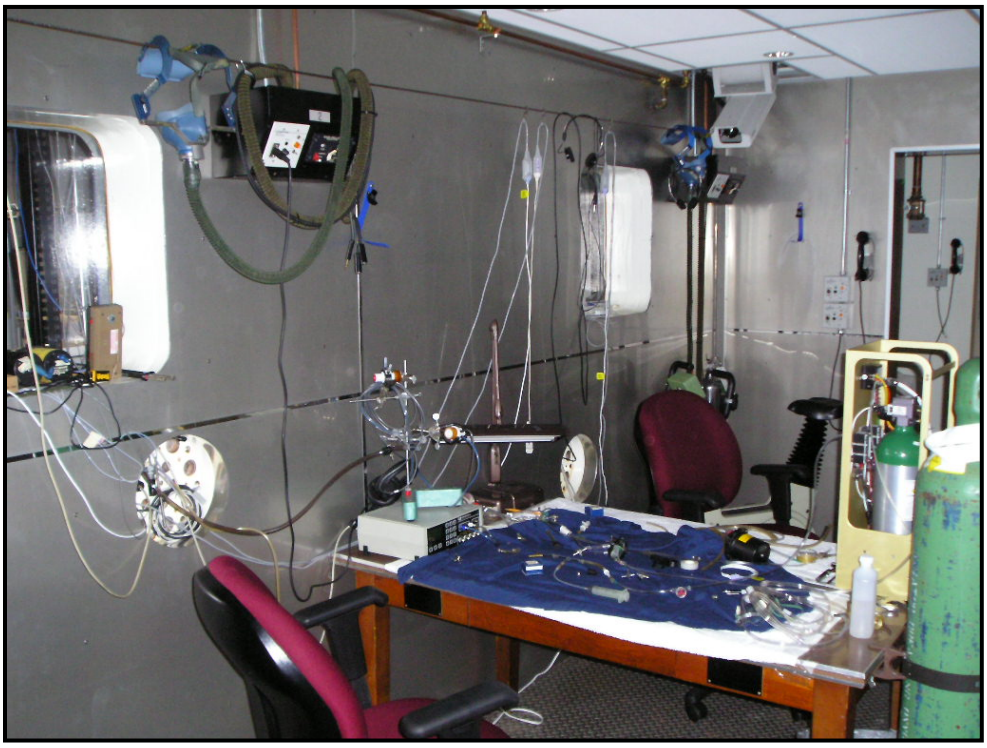

Figure 7. FAA Research Hypobaric (Altitude) Chamber.

Procedures

The objective measurements of efficacy included cardiac function (pulse rate), pulse oximetry (as an indication of peripheral oxygenation) using non-invasive automated physiological recording equipment/software. This included Labview® coupled with a forehead reflectance oximeter (figure 8a) which was backed up with an Onyx II pulse oximeter (figure 8b) (Yamaya et al., 2002). Additionally, color vision testing using the Ishihara pseudo isochromatic plates (blue-yellow wavelength) (figure 8c) (Vingrys & Garner, 1987) as an indicator of central oxygenation / hypoxia was used. Below 10,000 ft very few normal individuals notice any symptoms from hypoxia, even though measurable deficiencies in color and night vision exists (Pickard, 2002). Additionally, Vingrys and Garner (1987) showed a reliable and reproducible decrement in color vision in the blue/yellow wavelengths using the Farnsworth-Munsell Hue desaturation test at the moderate altitude of 12,000 ft. Oximetry is also a widely used and validated clinical tool throughout medical facilities. Heart rate and SpO_2 (oxygen saturation of Hemoglobin) values as obtained with pulse oximetry was automatically recorded using the Labview® system (figure 9). Two settings on the Oxygen Pulse Controller (OPC) were used in conjunction with evaluating the mask: “F20” and “R/M”. For an explanation of the OPC and the various settings please refer to Curry and Roller, 2007. The rationale for choosing these two settings is explained in the Discussion Section of this report.

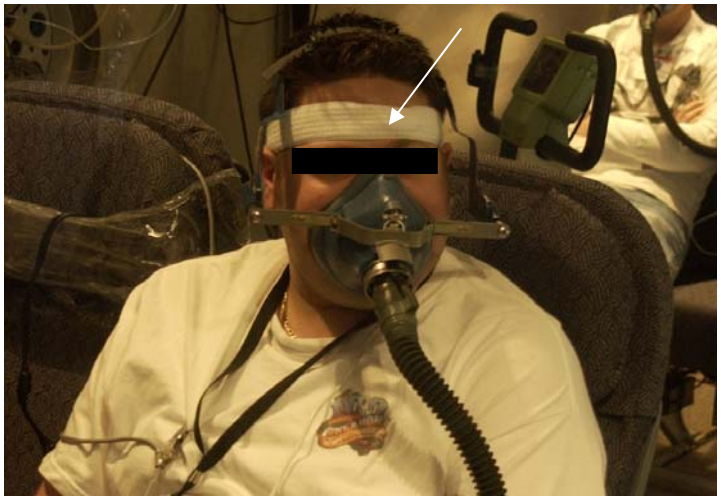

Figure 8a. Forehead Reflectance Oximeter.

Figure 8b. Onyx II® Digital Pulse Oximeter.

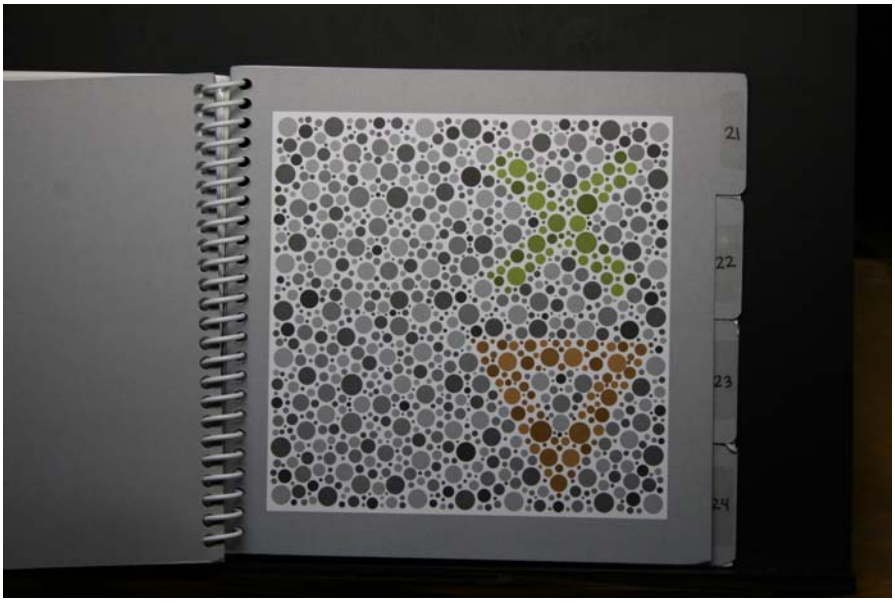

Figure 8c. Blue/yellow Pseudo Isochromatic Vision Plates.

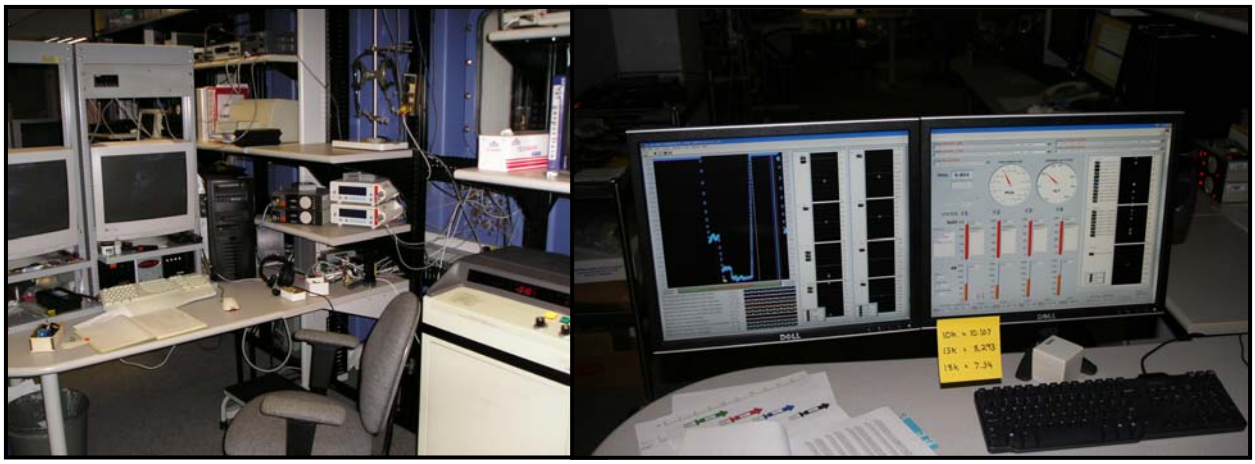

Figure 9. Data acquisition equipment, FAA.

During the testing period, there were a total of three separate ascents (altitude profiles) each involving six subjects at a time with two investigators monitoring in the chamber. A total of 19 subjects were tested:

a. During the first two ascents the subjects were at rest and not exercised.

(1) During Ascent 1 (table 1 and figure 10) the subjects were on chamber oxygen via the standard chamber face mask during the actual ascent portion. Once each discrete target altitude (10,000, 15,000, and 18,000 ft) was reached the subjects went off oxygen while their SpO_2, pulse rate and color vision were measured for signs of hypoxia. Based on prior studies (Pickard, 2002; Stepanek, 2002; Curry & Roller, 2007) it was estimated that hemoglobin desaturation of each subject would occur fairly rapidly (1 to 2 min) once they were off oxygen at altitude; and each would equilibrate with the ambient air. This technique of "going off oxygen" at altitude is routinely employed during altitude chamber training to allow aircrew to experience and recognize the symptoms of hypoxia. In fact during training, aircrew may go off oxygen for periods up to five minutes (at 25,000 ft PA) to adequately experience the effects of hypoxia. There have been no lasting effects shown in doing this (Pickard, 2002; Stepanek, 2002; Webb & Pilmanis, 2005; Webb et al., 2005). This ascent profile allowed the establishment of a "baseline" and control from which data from the other three ascents were compared.

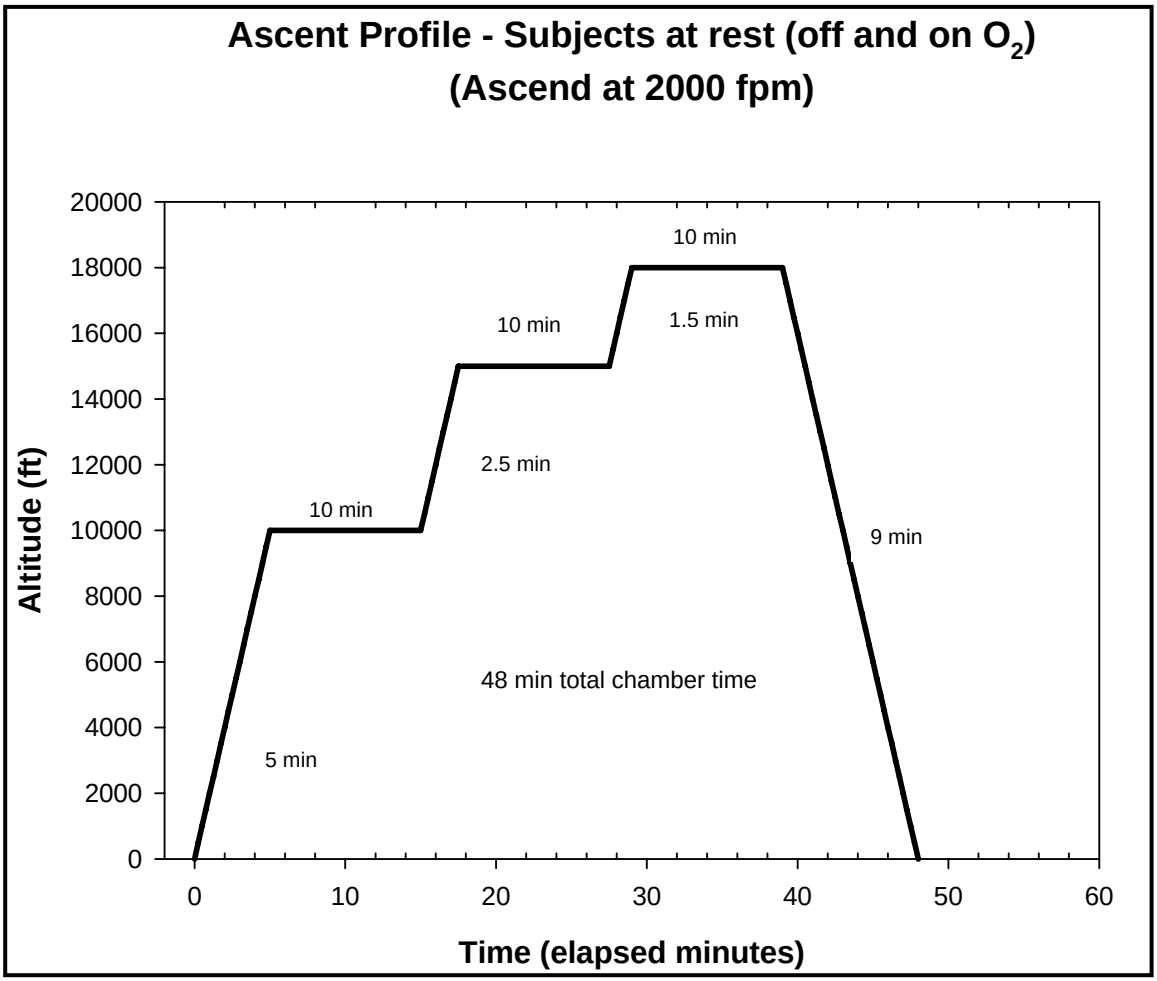

Figure 10. Altitude profile for rest.

(2) During Ascent 2 (table 1 and figure 10) each subject inspired oxygen via the Gentex® PHODS Mask (connected to the Aqualing® PHODS) during the entire altitude profile exposure. All subjects were monitored for signs and symptoms of hypoxia continuously. This exposure allowed us to evaluate the efficacy of the experimental system in providing oxygen at altitude for the prevention of hypoxia. Data from the Ascent 2 profile allowed the comparison of the efficacy of the mask to the nasal cannula (previous study) during exercise in preventing hypoxia.

b. During Ascent 3 (table 1 and figure 11) the subjects were exercised to 150% of their resting heart rate at each altitude utilizing a cycle ergometer (figure 12). The subjects ascended at rest and then exercised once each target altitude (10,000, 15,000, and 18,000 ft) was reached. Subjects were on oxygen using the experimental system at all times during these two ascents. Heart rate and SpO_2 were monitored continuously. Once the target heart rate was reached, color vision was evaluated. These physiological measurements were used to estimate the efficacy of O_2 delivery. The data from this profile was compared to that from Ascents 1 & 2 as well as the data from the previous USAARL testing involving the PHODS used with nasal cannula. Each subject served as his/her own control.

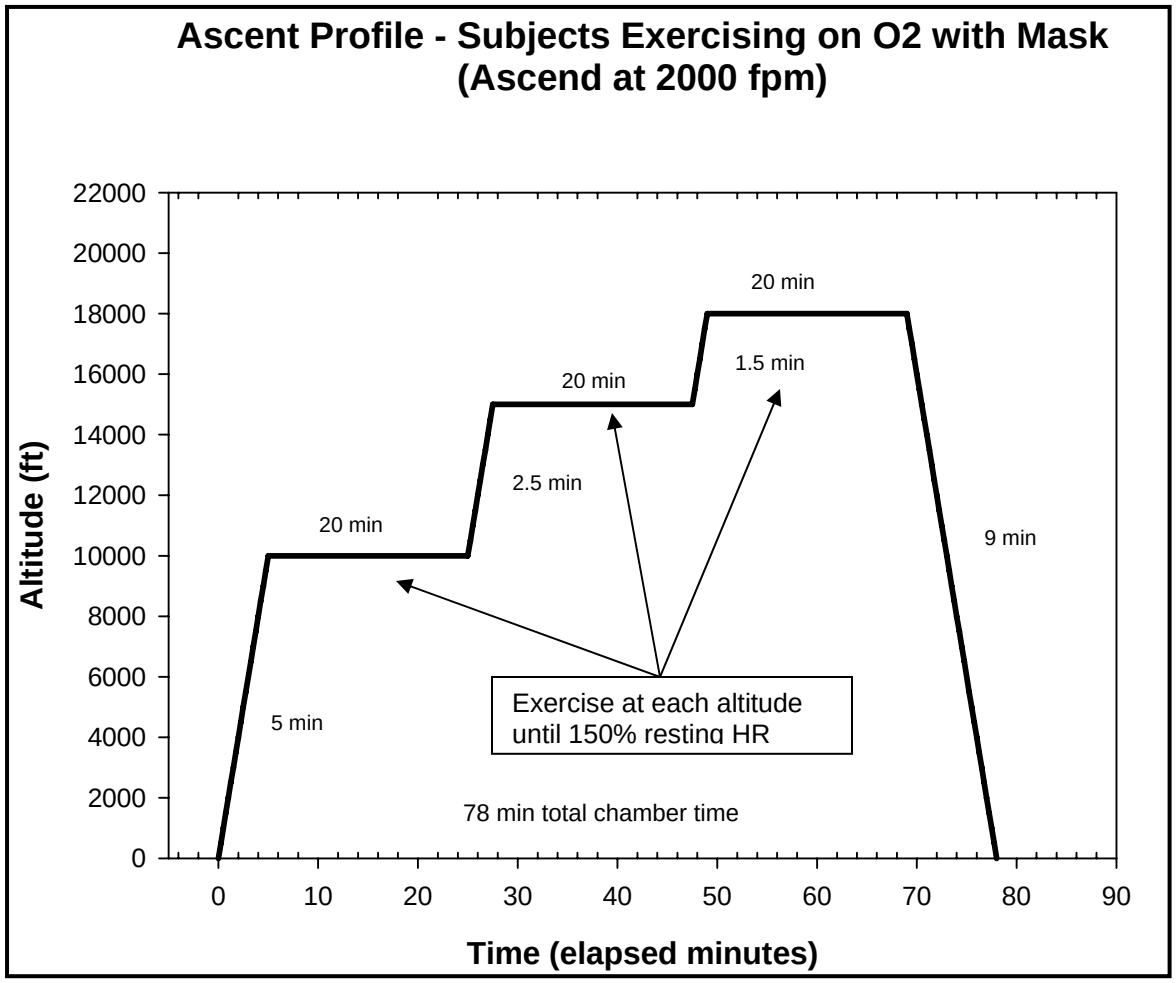

Figure 11. Altitude profile for exercise.

Table 1 illustrates the timings and procedures followed during the study. The times illustrated in figures 10 and 11 are fixed times for the altitude profile and agreed in advance with the FAA Altitude Chamber staff.

Table 1.
Experimental profile (See figures 10 and 11).

	AMBIENT BAROMETRIC PRESSURE	**AT REST OFF AND ON OXYGEN (TWO SEPARATE BUT IDENTICAL PROFILES)**	**EXERCISE ON OXYGEN (MASK) (ONE PROFILE)**
SEA LEVEL	760 mm Hg (1 ATM)	5 min equilibration then record pulse rate, oxygenation and hue desaturation test	Exercise to 150% resting heart rate then record pulse rate, oxygenation and hue desaturation test
10,000 ft	523 mm Hg (0.69 ATM)	5 min equilibration then record pulse rate, oxygenation and hue desaturation test	Exercise to 150% resting heart rate then record pulse rate, oxygenation and hue desaturation test
15,000ft	430 mm Hg (0.57 (ATM)	5 min equilibration then record pulse rate, oxygenation and hue desaturation test	Exercise to 150% resting heart rate then record pulse rate, oxygenation and hue desaturation test
18,000ft	380 mmHg (0.50 ATM)	5 min equilibration then record pulse rate, oxygenation and hue desaturation test	Exercise to 150% resting heart rate then record pulse rate, oxygenation and hue desaturation test

Figure 12. Cycle ergometer used for exercise.

The ascent and descent was between 3,000 and 5,000 feet per minute. The ascent/descent profiles are illustrated in figures 10 and 11.

Data analysis

The sample size for historical controls was already known (Curry & Roller, 2007). These previous data suggested that the minimal number of subjects needed for a statistically-significant difference was 16. Therefore, 20 volunteers were enrolled as test subjects of whom one was excluded for medical reasons.

Data were analyzed using SigmaPlot® for descriptive graphing and SigmaStat® for the inferential portion.

Repeated measures two-way analysis of variance (ANOVA) (Snedecor & Cochran, 1980; Sokal & Rohlf, 1995; Steel & Torrie, 1980) using altitudes (n=4) and test conditions (n=3) as the independent variables were performed to compare means and account for total population variance. If the ANOVA suggested rejection of the null hypothesis (no difference) then the data was analyzed using *a posteriori* hypothesis testing (Duncan's or Holm-Sidek methods) for multiple comparisons to determine which variables significantly differ. An α level of < 0.05 was considered significant.

Results

Device efficacy

Mean SpO_2 declined significantly as altitude increased when the subjects were off oxygen (figure 13) with an increase in heart rate. This decrease dropped below the criterion value of 91% (figure 13). With the mask (F20 and R/M) and PHODS in use, mean SpO_2 levels at rest were above 91%; significantly better than without supplemental oxygen (figure 14). This was also observed in the previous study of the PHODS with nasal cannula. The mask (R/M) condition maintained SpO2 at a significantly higher level ($p < 0.05$, 2 way ANOVA) at each altitude than mask (F20) or cannula at rest (figure 14). There were no significant changes in color vision with increasing altitude.

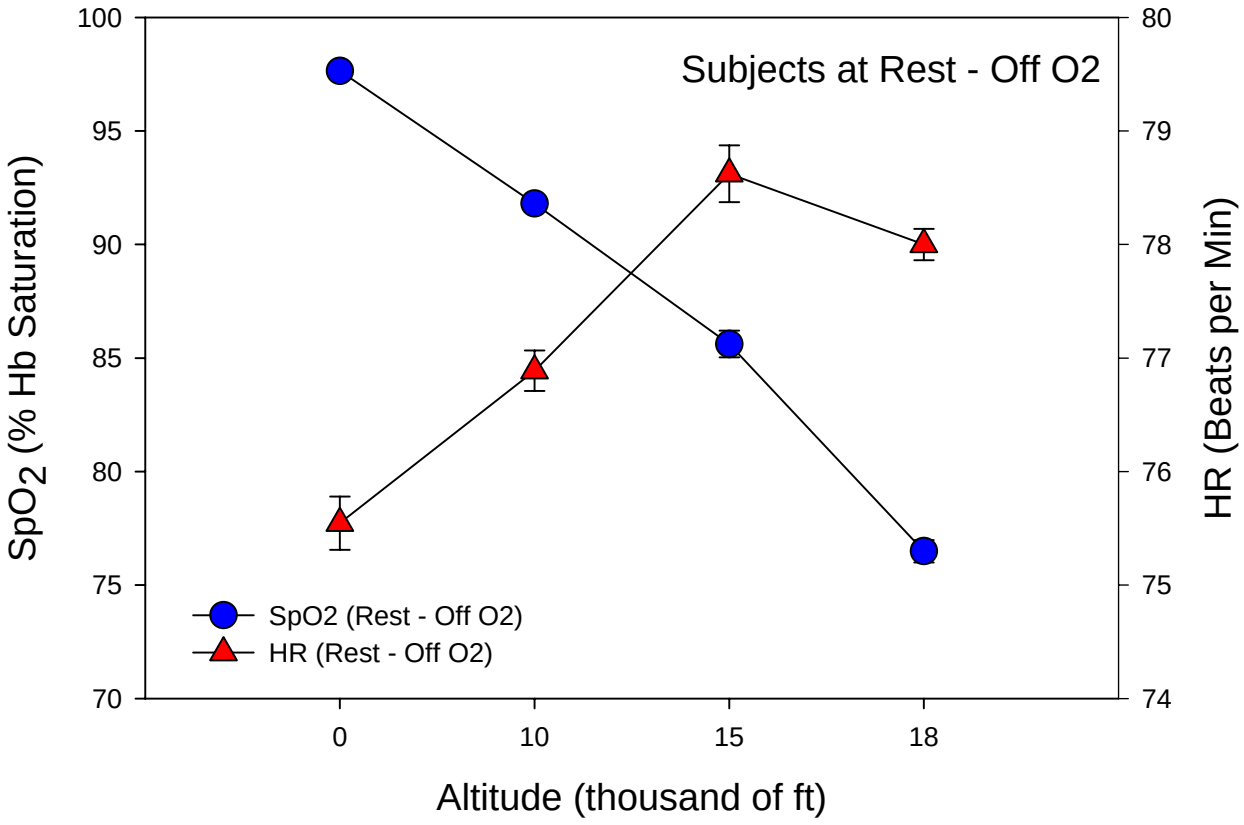

Figure 13. SpO_2 vs. Altitude for subjects at rest off oxygen.

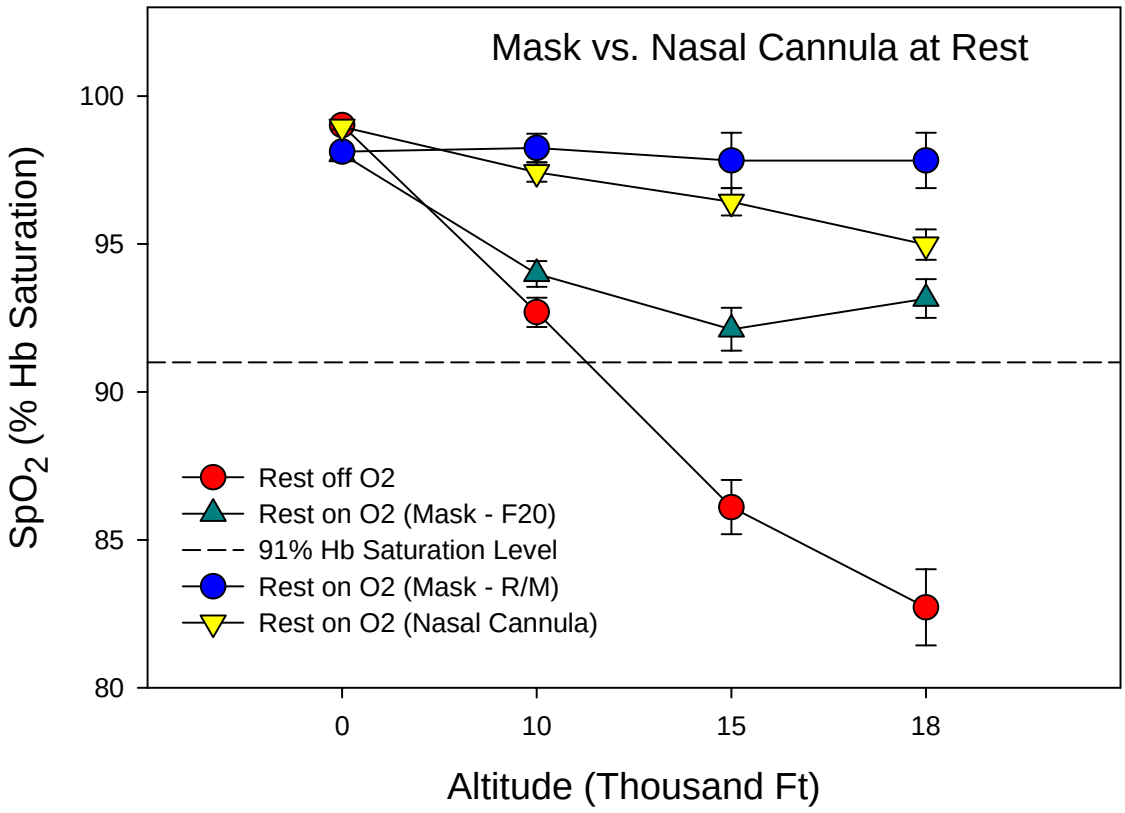

Figure 14. SpO_2 vs. Altitude for mask and cannula at rest.

Post exercise SpO_2 was significantly lower ($p < 0.05$, 2 way ANOVA) than rest for the mask (F20) condition at 18,000 feet but not at the other altitudes (figure 15).

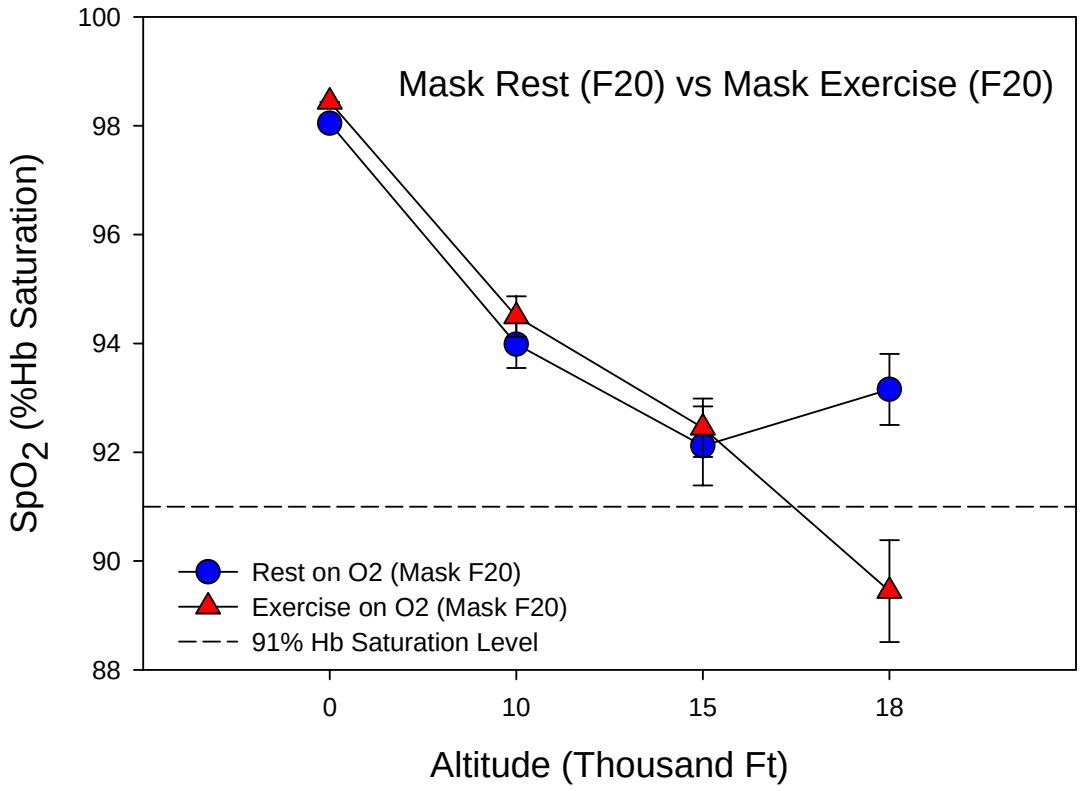

Figure 15. SpO_2 vs. Altitude for mask F20 (rest vs. exercise).

Comparing the mask (F20) and cannula at rest, the cannula provided significantly better oxygenation ($p < 0.05$, 2 way ANOVA) at 10,000 and 15,000 feet but they were statistically equivalent at 18,000 feet. It should be noted that at no stage did either device allow the SpO_2 to drop below 91% (figure 14).

Comparing the mask (F20) and cannula during exercise, there was a main effect of decreasing SpO_2 with increasing altitude for both devices ($p < 0.05$, 2 way ANOVA) (figure 16). However, neither device performed better than the other at any altitude ($p > 0.05$, 2 way ANOVA). Again it should be noted that at 18,000 feet both devices failed to maintain the SpO_2 above 91%, however the variance of the data at this altitude suggests that oxygenation would be very close to the criterion level (figure 16).

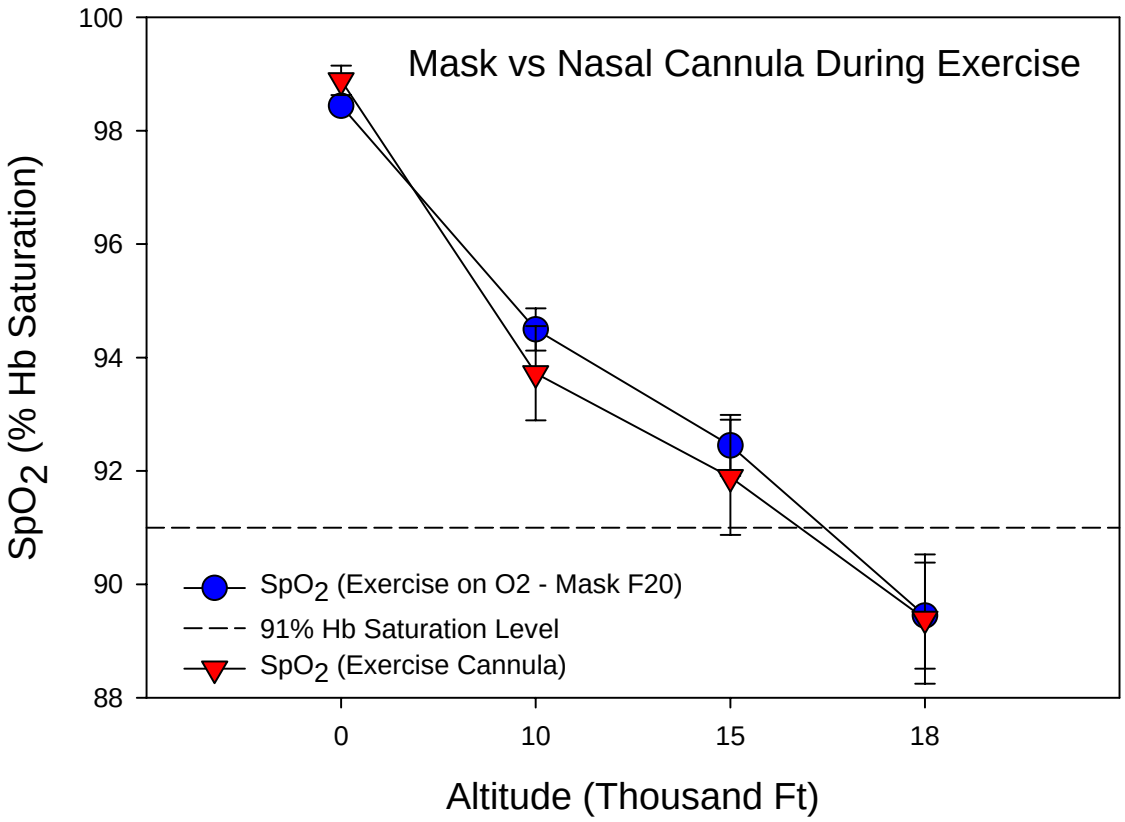

Figure 16. SpO_2 vs. Altitude for mask and nasal cannula during exercise.

Oxygen utilization/consumption

Oxygen consumption (g O_2/Kg-hr) and bottle O_2 endurance (hours) was calculated from all chamber runs and is presented in table 2. The data suggest that the Mask on a setting of R/M utilizes more O2 than either the mask on F20 or the nasal cannula and thus has a bottle endurance of less than one hour. The cannula provided the longest bottle endurance of approximately three hours at rest.

Table 2.
Oxygen consumption and bottle endurance.

	VO_2 (g/Kg/hr)	**Bottle endurance (hours)**
Rest – Cannula	0.3 ± 0.03	3.0 ± 0.4
Rest – Mask F20	0.3 ± 0.03	2.3 ± 0.16
Rest - Mask R/M	1.1 ± 0.25	0.8 ± 0.13
Exercise – Mask F20	0.4 ± 0.03	2.0 ± 0.2

Discussion

All subjects when exposed to increasing altitude off O_2 exhibited an appropriate physiological response of increased heart rate in response to decreasing SpO_2 (figure 13). The data illustrates that the mask (F20) and nasal cannula during conditions of rest maintain the SpO_2 above the upper criterion level of 91% (figure 14). During exercise both the mask (F20) and cannula were statistically equivalent throughout all altitudes ($p < 0.05$, ANOVA) and maintained SPO_2 above the upper criterion level at altitudes up to and including 15,000 ft PA; however, at 18,000 ft PA both devices allowed a drop below 91% SpO_2 (figure 16). It should be noted that the variance in data at 18,000 ft PA for both devices shows an equal range above and below 90% SpO_2 (figure 16).

Mask (F20) shows no difference in subject oxygenation between rest and exercise conditions (figure 15) up to and including 15,000 ft PA. However, at 18,000 ft PA there is a statistically significant drop in SpO_2 with exercise ($p < 0.05$).

The R/M setting for the mask was only tested under conditions of rest due to time constraints. This setting was envisaged as an emergency setting for respiratory distress or extreme physical exertion. The results (figure 14) show that subjects were maintained at sea level SpO_2 up to and including 18,000 ft PA.

The VO_2 data (table 2) show that the PHODS with cannula allow for lower consumption with resulting longer bottle endurance than for the mask at either setting. The mask (F20) during exercise shows a small increase in VO_2 over rest and therefore shorter bottle endurance. Based on the VO_2 comparison for the mask (F20) and the cannula one would assume that SpO_2 of the subjects using the mask would have been significantly higher than the cannula; however, this

was obviously not the case. It is probable that the higher VO_2 illustrated by the mask (F20) was not an accurate reflection of oxygen consumption by the subjects but was in fact a reflection of oxygen drawn into the mask, some of which would have been vented through the mask's exhaust port with each exhalation; and therefore not available for physiological use.

Conclusions

The mask (F20) and cannula in conjunction with the PHODS are statistically equivalent ($p > 0.05$) and provide optimal oxygenation at rest and adequate oxygenation during exercise. The bottle endurance is superior with the nasal cannula but still over two hours with the mask on F20 setting. It is evident from our data that the mask on a setting of R/M while providing superior oxygenation at rest results in much shorter bottle endurance (< 1 hr). Therefore while appropriate during emergencies this setting should be used with caution unless there is an adequate supply of oxygen on board the aircraft.

Given the equivalence of the cannula and mask (F20) the only advantage of the mask would appear to be for those individuals who have difficulty using the cannula because of nasal obstruction or mouth breathing. The results of this study show that the mask tested is a safe alternative oxygen delivery method for use with the PHODS when properly used by trained aircrew.

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